UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION)))	MDL No. 1456
	_)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO: County of Suffolk v. Abbott Labs., et al., (E.D.N.Y. No. CV-03-229))	Judge Patti B. Saris
	,	

INDIVIDUAL RESPONSE OF WARRICK PHARMACEUTICALS TO SUFFOLK COUNTY'S SUPPLEMENTAL FILING IN RESPONSE TO THE COURT'S OCTOBER 26, 2004 ORDER

Warrick Pharmaceuticals Corporation ("Warrick") joins the Response of the Suffolk 13 + 6 Challenging Suffolk County's Supplemental Filing In Response to the Court's October 26, 2004 Order ("Response of the Suffolk 13 + 6"). In addition, Warrick responds more specifically that the County of Suffolk ("Suffolk") has failed to produce or describe *any* methodology for calculating the so-called "spread" for any of Warrick's drugs, in contravention of the Court's October 26, 2004 Order (the "Order"). Suffolk's method of calculation relies on a ratio that, by its own terms, does not apply to generic or multiple-source drugs, and Warrick manufactures generic and multiple-source drugs exclusively. Therefore, because Suffolk has failed to produce a methodology for its calculation of spreads for Warrick products, Suffolk's AWP claims against Warrick should be dismissed.

Suffolk's flawed methodology is founded upon the premise that "for prescription drugs, '[i]n the United States, the average retail price is estimated to be 1.27 times the true average wholesale price." Affidavit of Aaron D. Hovan ¶ 3, 14 (quoting J. Graham and B. Robson,

Prescription Drug Prices in Canada and the United States - Part I: A Comparative Survey at n.1, attached to Hovan Aff. as Ex. J.). Proceeding on this premise, Suffolk then applies the "1.27 ratio" to retail prices of Warrick's pharmaceuticals to determine the "estimated true AWP." Id. ¶ 6. This "estimated true AWP" is then compared to published AWP, less Medicaid reimbursement, "to arrive at an estimated overcharge, or 'spread' for each drug and dosage." Id. ¶ 7.

The "1.27 ratio" is derived from a footnote in an article issued by a Canadian research organization, which states that "[i]n the United States, the average retail price is estimated to be 1.27 times the true average wholesale price (US Department of Health and Human Services 2000:98)." Hovan Aff. ¶ 14 (quoting J. Graham and B. Robson at n.1).¹ This one-sentence footnote, in turn, is based upon a single page in a 2000 report from the United States Department of Health and Human Services. Graham and Robson at n.1 (citing Dep't of Health and Human Services, *Prescription Drug Coverage, Spending, Utilization, and Prices* 98 (2000) (the "HHS Report," the relevant pages of which are attached hereto as Exhibit A)). Page ninety-eight of the HHS Report is the <u>only</u> basis Suffolk provides for its "1.27 ratio.' *See* Response of the Suffolk 13 + 6 at 5-6.

Although the Graham and Robson article is not the ultimate source of the "1.27 ratio," it is striking to note that *the article does not consider a single Warrick drug at issue in this case*. In fact, the authors explicitly exclude Albuterol Aerosol from the article's wholesale and retail price comparisons. *See* Hovan Aff., Ex. J, Method at 2-4.

Plaintiffs also claim that they "confirmed the reasonableness of the 1.27 ratio with others," but they fail to document this assertion, notwithstanding the Court's Order that Suffolk "disclose within three weeks *all* documents upon which it relied in calculating the spreads." Order at 4 (emphasis added). Moreover, one of the individuals with whom Suffolk claims it "confirmed" the ratio, Steven Schondelmeyer, has himself distinguished between the pricing practices for generic and brand-name drugs. *See* Schondelmeyer Dep. Tr. at 213: 19-21 ("...I

In addition to the multitude of methodological errors described in the Response of the Suffolk 13 + 6 and notwithstanding any possible relevance to branded pharmaceuticals, the propounded ratio simply does not apply to generic or multiple-source drugs. The cited page of the HHS Report consists almost entirely of Table 3-1, which is entitled "Illustrative Example of Pricing for *Brand Name Prescription Drugs*." HHS Report at 98 (emphasis added). The first note to the table explains that "prices are based on a composite of several commonly prescribed *brand-name drugs*." *Id.* (emphasis added). Indeed, the prior page introduces the table by stating it merely "portrays illustrative pricing for *brand name drugs*." *Id.* at 97 (emphasis added). Furthermore, the HHS Report explicitly reveals its rationale for excluding generic drugs:

Actual price relationships vary substantially by drug, and *are quite different for generic drugs*. Generic drugs, for example, have much lower prices on average and the fixed costs for the pharmacy of dispensing the prescription represent a much higher proportion of the final retail price. Furthermore, *approaches to pricing generic drugs in the industry are different*.

Id. (emphasis added). Thus, the "1.27 ratio" -- whatever its supposed applicability for branded drugs -- is expressly inapplicable to generic drugs because the price relationships for generic drugs are "quite different."

Suffolk has clearly failed to produce the information required by the Court in its Order.

On its face, the methodology offered by Suffolk does not apply to generic or multiple source drugs. Because Warrick manufactures only generic and multiple-source drugs, the methodology does not apply to Warrick products. Suffolk therefore lacks a good faith basis for calculating the spread for Warrick products, and, accordingly, the Court should dismiss Suffolk's AWP claims against Warrick.

know that in general generics are, have been and were substantially more discounted and rebated than brand name products.") (attached hereto as Exhibit B).

Respectfully submitted,

WARRICK PHARMACEUTICALS CORPORATION

By its attorneys,

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Dated: November 30, 2004

CERTIFICATE OF SERVICE

I hereby certify that on November 30, 2004, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Eric P. Christofferson____

Eric P. Christofferson